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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/802,685 | 03/09/2001 | Gary Van Nest | 377882001600 | 9970 |

25226 7590 08/20/2003
MORRISON & FOERSTER LLP
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EXAMINER

WOITACH, JOSEPH T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

13

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/802,685

Applicant(s)

NEST ET AL.

Examiner

Joseph T Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1 and 5-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This application filed March 9, 2001, claims benefit to provisional application 60/188,302, filed March 10, 2000.

Applicants' amendment filed May 27, 2003, paper number 12, has been received and entered. Claims 8-10 have been amended. Claims 1-10 are pending.

Election/Restriction

Applicant's election with traverse of Group I, claims 1, 5-7 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that relationship of the invention is not combination-subcombination, rather it is a genus-species relationship. Pointing to specific embodiments in the claims Applicants argue that claim sets forth a sequence representing a genus and that specific sequences set forth in claims 2-4 represent specific species comprised within this genus. Additionally, Applicants note the amendments to the claims and argue that the kits now claimed in claims 8-10 relate to generic claim 7. This is not found persuasive because claims 2-4 and claims 8-10 encompass specific nucleic acid sequences which are not even generically set forth in claims 1 and 7, respectively. Each of the dependent claims set forth specific sequences which comprise additional nucleic acid bases. While it is noted that claims 1 and 7 use open language with respect to the ISS sequence set forth, claims 2-4, 8-10 do not further define only the particular pyrimidine in claim 1 and 7, they also add other nucleic acid

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bases to the ends. Clearly these are different and specific nucleic acid sequences which would not anticipate nor make obvious one another as ISS sequences.

With respect following the criteria of MPEP 806.05(c), examiner notes that the classification is the same for each of the groups, however, the search required for each of the particular sequences recited in the claims are not the same nor co-extensive. A search of a sequence set forth in group I will not necessarily identify the sequence set forth in any other claim or group because they set forth additional sequence requirements. With respect to a different status in the art, it is well established that specific ISS sequences have dramatically different properties based on the specific sequence. In the instant case, the addition of nucleotide base(s) to the ends of another sequence would produce a structurally different product and in view of the art may produce a functionally different product. Therefore, two of the three requirements have been satisfied in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are pending. Claims 2-4, 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12. Claims 1, 5, 6 and 7 are currently under examination as they are drawn to a method of reducing severity of a symptom of a virus infection by administering the ISS 5'-C, G, pyr, pyr, C, G-3', and a kit containing said ISS sequence.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7 and 11 of Application No. 09/802,686 (Pub No. US 2001/0046967). Although the conflicting claims are not identical, they are not patentably distinct from each other because each are directed to use of the same ISS sequence for reducing the severity of a virus infection. It is noted that 09/802,686 recites treatment of a RSV infection which would anticipate the treatment of any virus as instantly claimed. Further, it is noted that the instant application has a different inventive entity from that of US 2001/004696A1 and includes the additional inventor Joseph J Eiden, however the effective filing date March 10, 2000, is the same as the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6 and 17 of Application No. 09/802,445 (Pub No. US 2001/0107212 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because each are directed to use

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of the same ISS sequence for reducing the severity of a virus infection. It is noted that 09/802,686 recites treatment of a symptoms of papillomavirus infection which would anticipate the treatment of any virus as instantly claimed. Further, it is noted that the instant application has a later filing date from that of US 2001/0107212 A2 but has the same inventive entity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg *et al.* (US Patent 6,218,371 B1 -IDS Reference).

Claim 1, 5 and 6 are drawn to a method of reducing severity of a symptom of a virus infection by administering the ISS 5'-C, G, pyr, pyr, C, G-3', and claim 7 is drawn to a kit containing said ISS sequence. Krieg *et al.* teach ISS sequences and the use of said sequences to

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stimulate the immune system (column 8, lines 32-45). In animals, Krieg *et al.* teach that the ISS sequences can be used to treat viral infections (column 9, lines 6-8 and starting at line 42 through column 10). Krieg *et al.* teach various methods and among the conditions tested is the administration of the ISS sequence alone (see figure 8 for example). Finally, Krieg *et al.* teach a variety of consensus sequences and specific sequences for use in the disclosed methods, in particular specific sequences which anticipate a sequence comprising 5'-C, G, pyr, pyr, C, G-3' (see for example SEQ ID NO: 13 and 14). With respect to the kit, Krieg *et al.* specifically discloses providing the materials necessary to treat an individual (see column 22, lines 27-42; and column 26, lines 40-50). In this case the use of the kit is not seen as providing patentable weight to the claimed invention for reasons of record. The CAFC in *In re Gulack* 217 USPQ 401 1983 stated that printed matter that is not functionally related to the substrate does not distinguish the invention from the prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight (page 401). The court further stated that the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate (page 404 "B"). Since ISS sequences were well known and used to stimulate the immune response to viral infections, and Krieg *et al.* specifically teach a sequence which anticipates a sequence comprising 5'-C, G, pyr, pyr, C, G-3' the claim to the kit is also anticipated.

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Claims 1, 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg *et al.* (US 2003/0050263 A1).

Claim 1, 5 and 6 are drawn to a method of reducing severity of a symptom of a virus infection by administering the ISS 5'-C, G, pyr, pyr, C, G-3', and claim 7 is drawn to a kit containing said ISS sequence. Krieg *et al.* teach ISS sequences and the use of said sequences to stimulate the immune system, and in mammals, Krieg *et al.* teach that the ISS sequences can be used to treat viral infections (paragraphs 14-20). Krieg *et al.* teach various methods and among the conditions tested is the administration of the ISS sequence alone (see working example). Finally, Krieg *et al.* teach a variety of consensus sequences and specific sequences for use in the disclosed methods, in particular specific sequences which anticipate a sequence comprising 5'-C, G, pyr, pyr, C, G-3' (see for example SEQ ID NO: 14 and 15). With respect to the kit, Krieg *et al.* specifically discloses providing the materials necessary to treat an individual. In this case the for the use of the kit is not seen as providing patentable weight to the claimed invention for reasons of record. The CAFC in *In re Gulack* 217 USPQ 401 1983 stated that printed matter that is not functionally related to the substrate does not distinguish the invention from the prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight (page 401). The court further stated that the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate (page 404 "B"). Since ISS sequences were well known and used to stimulate the immune response to viral infections, and Krieg *et al.* specifically teach a sequence which

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anticipates a sequence comprising 5'-C, G, pyr, pyr, C, G-3' the claim to the kit is also anticipated.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Raz *et al.* (US 2003/0050263 A1) teach that ISS sequences alone, which are similar but not encompassed by those set forth in the present application, are capable of affecting the immune system of a subject by shifting host's immune response to a TH1 type immune response. This shift is affected by the delivery of an ISS sequence can enhance the immune response of the host by increasing the immunogenicity to foreign antigen(s) already present in the host.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


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